

# EXHIBIT 11



# Midurethral slings: which should I choose and what is the evidence for use?

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## Purpose of review

Midurethral slings are currently the most commonly performed surgeries for stress urinary incontinence (SUI). This review examines the pros and cons of the main types of midurethral slings that are available for the surgical treatment of SUI – full-length retropubic, full-length transobturator, and single-incision slings – to assist patients and physicians in choosing between them.

## Recent findings

Comparative studies have shown that full-length retropubic and transobturator midurethral slings have similar efficacy but differ in their risk profiles; retropubic slings have higher rates of bladder perforation whereas transobturator slings have more groin pain and dyspareunia. When a certain type of single-incision sling is excluded from systematic reviews, single-incision slings appear comparable to standard midurethral slings.

## Summary

Both full-length midurethral slings – retropubic and transobturator – are reasonable for the surgical treatment of SUI. The decision to choose one or the other should be individualized based on patient preference after counseling about the risks of each. More recent data suggest that the currently available single-incision slings may be comparable.

## Keywords

midurethral sling, retropubic sling, single-incision sling, tension-free vaginal tape, transobturator tape

## INTRODUCTION

Stress urinary incontinence (SUI), the involuntary loss of urine on effort or physical exertion such as cough and strain [1], affects the quality of life of millions of women. It can be conservatively treated with pelvic floor muscle exercises or pessaries, or it can be treated surgically; 13.6% of women in the United States have at least one surgery for SUI in their lifetime, resulting in 260 000 continence surgeries per year [2,3]. Traditional surgeries for SUI, including retropubic urethropexies and pubo-vaginal slings, are as effective as midurethral slings but are more invasive, cause more voiding dysfunction and de-novo urgency incontinence, and involve longer recovery times [4]. Therefore, midurethral slings have largely replaced traditional surgery for SUI and are now the most commonly performed surgeries for this condition. The purpose of this review is to present the current evidence for each type of midurethral sling: full-length retropubic, full-length transobturator, and single-incision mini slings. The midurethral slings we refer to in this review are all type 1 wide pore monofilament

polypropylene mesh and are placed in a tension-free fashion. We do not include other types of mesh or biologic products that have not been shown to be as well tolerated or effective as type 1 polypropylene mesh slings. We will not comment on adjustable slings for which there are insufficient data to date.

## MIDURETHRAL SLING THEORY AND DEVELOPMENT

The first midurethral sling was a retropubic tension-free vaginal tape (TVT) developed by Petros and Ulmsten in the 1990s [5,6]. This sling is a 1 cm by

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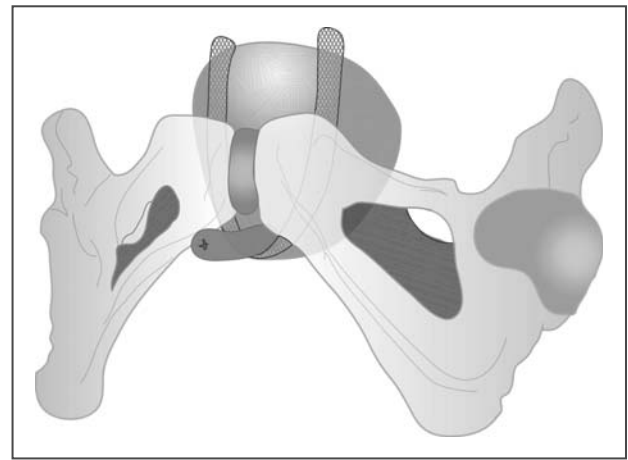
## KEY POINTS

- Retropubic and transobturator full-length midurethral slings have high success rates that are generally comparable.
- Retropubic midurethral slings have higher rates of voiding dysfunction, bleeding, and bladder injury than transobturator slings, whereas transobturator slings have higher rates of vaginal perforation and groin pain and may have long-term cure rates.
- Currently available mini slings may be comparable to full-length midurethral slings, but there is no clear advantage to their use over full-length slings.

40 cm polypropylene mesh placed at the midurethra in a tension-free fashion that travels behind and exits above the pubic symphysis. It was developed based on the Integral Theory of continence that suggests that continence is maintained at the midurethra (rather than the bladder neck targeted by traditional slings) by pubovaginal ligaments and a vaginal hammock that support the urethra. The location and tension-free technique were new and found to be efficacious, and these slings could be performed in an outpatient setting. In 2001, the transobturator sling was introduced to address the low but serious risks of adverse events such as bowel, bladder, and vascular injuries from the blind retro-pubic passage of the trocars [7]. As described in further section, these transobturator slings act in a similar, midurethral, tension-free fashion but attempt to mitigate some of the risks by exiting through the obturator muscles and membrane avoiding the retropubic space. Mini slings were subsequently developed that were about 8 cm long requiring only a vaginal incision and anchoring just beyond the vagina without completely traversing the retropubic space or perforating completely through the obturator structures.

### RETROPUBIC MIDURETHRAL SLING

Retropubic midurethral slings are positioned under the midurethra and behind the pubic bone (Fig. 1). The mesh is placed through a vaginal incision under the urethra, passed behind the pubic bone, and exits through two abdominal skin incisions. This can be performed by passing trocars via the bottom-up technique or placing the trocars first through the abdominal incisions and passing them through the vaginal incisions, attaching the mesh and drawing the mesh through the space. The 'u' shape of these slings has a theoretical advantage for women with

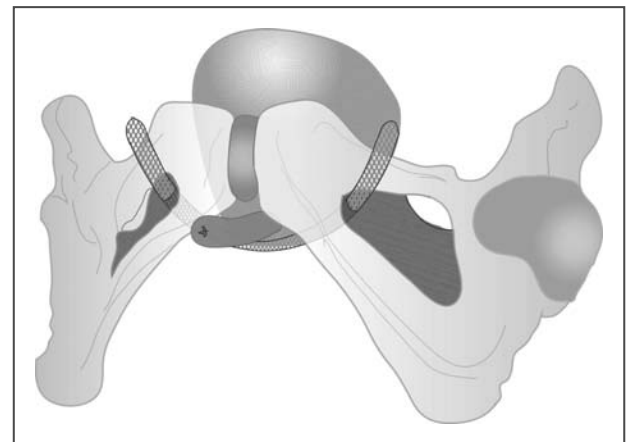


**FIGURE 1.** Retropubic sling. Courtesy of J.T.-K., MD.

weak urethras (intrinsic sphincter deficiency, ISD) because it potentially compresses the sides of the urethra more than the relatively flat transobturator sling. Another possible advantage for the retropubic sling is less mesh traversing the vagina than a trans-obturator sling, potentially decreasing the risk of vaginal pain and dyspareunia. The main disadvantage of the retropubic sling compared with single-incision and transobturator slings is the passage of trocars and mesh through the retropubic space with the potential for bladder and vascular injury.

### TRANSOBTURATOR SLING

Transobturator slings are positioned under the midurethra and laterally through the obturator membrane and surrounding tissues (Fig. 2). With an inside-out technique, the mesh is placed through a vaginal incision and then passed through the obturator internus muscle, obturator membrane, and obturator externus muscle to exit through the skin in the groin. With the outside-in technique,

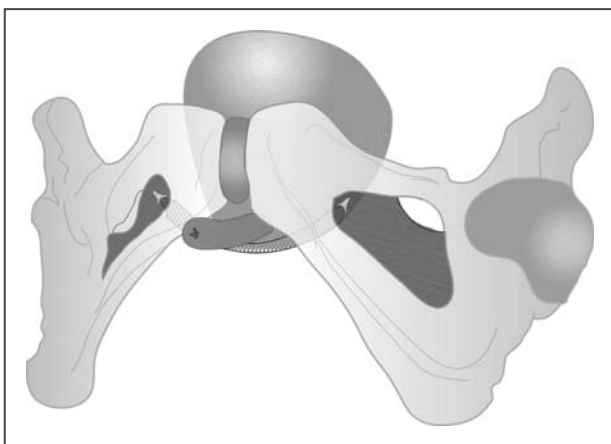


**FIGURE 2.** Transobturator sling. Courtesy of J.T.-K., MD.

the trocars are placed through the groin and out the vagina in the reverse direction and the mesh is connected to the tips of the trocar and brought through the vaginal incision and out through the groin. As mentioned earlier, these slings were designed to decrease the risk of bladder injury by avoiding the retropubic space, which is a possible advantage, particularly for some patients (history of vascular graft, transplanted kidney, bleeding diatheses, inguinal hernias, etc.). The presence of mesh lateral to the urethra in the vagina, however, may increase the risk of vaginal pain and dyspareunia, and the presence of mesh in the obturator muscles and near the adductor longus tendon may increase the risk of groin pain. The flatter trajectory of the mesh under the urethra has the theoretical disadvantage of compressing only the urethra in an anterior-posterior direction without lateral compression reducing the risk of urinary retention.

### SINGLE-INCISION MINI SLING

Single-incision mini slings can be placed through a single incision in the vagina either in a retropubic direction such that they are anchored to the urogenital diaphragm or in a transobturator direction anchored to the obturator internus muscle without traversing all the structures in the obturator foramen (Fig. 3). One possible advantage of no groin or abdominal incisions is that these slings are less painful and therefore more amenable to office procedures. Another possible advantage is that they use less mesh (8cm compared with 40cm) than full-length slings and do not traverse the retropubic space or transobturator membrane theoretically avoiding risk of damage to structures in and near the retropubic space as well as avoiding the risk of irritation and pain in the groin. Mini slings are of a fixed length and placed in fixed sites in the pelvis



**FIGURE 3.** Single-incision sling. Courtesy of J.T.-K., MD.

with anchors making them more difficult to adjust to the desired tension-free position once deployed.

### RETROPUBIC VS TRANSOBTURATOR SLINGS

The first and arguably best single study comparing retropubic and transobturator slings is the trial of midurethral slings (TOMUS trial), a randomized, controlled study of 597 women performed at multiple sites throughout the United States with 1, 2, and 5-year follow-up data [8,9,10<sup>¶</sup>]. At 1 year, objective success rates between the two slings met criteria for equivalence. Subjective success rates were slightly higher in women assigned to retropubic slings, but there were no differences in quality of life, satisfaction, or urge symptoms. The authors concluded that as efficacy was similar, patients should be counseled about their choices based on side-effects including higher voiding dysfunction in women with retropubic slings (2.7 vs 0%) and higher neurologic symptoms (9.4 vs 4%) in women with transobturator slings. Five years after surgery, women who had been randomly assigned to retropubic slings had slightly greater success rates defined as no retreatment or self-reported stress incontinence symptoms but slightly more urgency and a more negative impact on quality of life and sexual function. Satisfaction remained high in both the arms. A recent retrospective review of 1877 patients with slings performed at a single institution with median 10-year follow-up similarly found lower reoperation rates after retropubic compared with transobturator slings or mini slings ( $P=0.002$ ) [11]. A randomized controlled trial (RCT) in Finland with 5-year data and an excellent follow-up rate found no difference between retropubic and transobturator slings; success rates were over 80% in both the groups even when patients lost to follow-up were counted as failures [12].

A systematic review performed by the Society for Gynecologic Surgeons (SGS) of all RCTs with minimum 12-month follow-up through April 2013 also showed similar efficacy and satisfaction with the two types of full-length midurethral slings: slightly but not significantly higher objective and subjective success after retropubic slings and slightly but not significantly higher satisfaction after transobturator slings [13<sup>¶¶</sup>]. Sling erosion, groin pain, and vaginal perforation were higher with transobturator slings whereas operative time, bladder/urethral perforations, perioperative pain, urinary tract infections, and overactive bladder symptoms were higher with retropubic slings. Similar to the TOMUS trial, the SGS Review Group recommends either intervention for objective and subjective cure with the decision

based on which adverse events are of greatest concern to the patient. A Cochrane review similarly found slightly higher objective cure rates with retropubic compared with transobturator slings but no difference in subjective cure rates [4]. The adverse events blood loss, bladder perforations, and voiding dysfunction were higher with retropubic slings. The most recent systemic review of RCTs of midurethral slings echoed the results of the SGS and Cochrane reviews with somewhat better cure rates and lower rates of neurologic symptoms and vaginal pain with the trade-off of more bladder perforations and bleeding than with transobturator slings [14]. The same group performed a cost-effectiveness analysis of the two types of slings and found the transobturator midurethral sling to be more cost-effective with a difference of \$100 per quality-adjusted life-year [15].

There is more long-term follow-up of retropubic slings than transobturator slings, at least partly because they have been on the market longer. These studies suggest good durability of success rates over 10 and 17 years [16,17].

To summarize, based on these large studies, either retropubic or transobturator slings are reasonable, and the decision should be based on patient and surgeon preference after balancing all of the known pros and cons of each, including efficacy and risks. Surgeon preference often includes surgeon comfort with one technique over the other.

### **RETROPUbic TOP-DOWN VS BOTTOM-UP**

There are only two RCTs addressing the surgical approach for retropubic slings: passing the trocars and mesh arms through the vaginal incision, behind the pubic bone, and out the suprapubic incisions (bottom-up) or passing the trocars through the suprapubic incisions, behind the pubic bone, and out the vaginal incision (top-down) that are then connected to the mesh and drawn through the incision. These studies are small and showed similar efficacy and adverse events [18,19]. The SGS Systematic Review Group that only included RCTs found insufficient evidence to recommend one approach or the other [13], and a Cochrane review that included RCTs and quasi-RCTs found statistically significant improved efficacy with bottom-up slings, with less voiding dysfunction, bladder perforations, and mesh erosions [4].

To summarize, either top-down or bottom-up retropubic sling approaches are reasonable but comparisons are limited and there is some evidence to suggest superior outcomes and lower complications with bottom-up retropubic slings compared with top-down slings.

### **TRANSOBTURATOR INSIDE-OUT VS OUTSIDE-IN**

The SGS Systematic Review Group found insufficient evidence to recommend one approach or the other in terms of efficacy but did not compare adverse events [13]. One study found a higher rate of sexual dysfunction in out-to-in than in-to-out transobturator slings or retropubic slings [20], but this finding has not been reproduced in other studies comparing out-to-in transobturator with retropubic slings [21,22].

To summarize, either inside-out or outside-in transobturator approaches are reasonable.

### **SINGLE-INCISION MINI SLINGS VS FULL-LENGTH SLINGS**

When all mini slings were grouped together and compared with full-length slings, mini slings had higher dyspareunia rates than either retropubic or transobturator full-length slings and higher mesh erosion rates than retropubic full-length slings [13]. The SGS Systematic Review Group recommended traditional full-length slings to maximize cure rates. However, in this review, most of the mini sling trials studied the TVT-Secur. In the largest RCT of mini slings vs full length slings (included in the SGS review), the TVT-Secur mini sling placed in the 'u' position similar to a retropubic sling was compared with a full-length retropubic sling. This study found similar subjective cure rates but greater postoperative incontinence severity with the mini sling compared with the full-length sling [23]. A recent RCT of 122 women found no significant difference between the transobturator sling and TVT-Secur [24]. The TVT-Secur mini sling is no longer on the market. A systematic review that compared mini slings to full-length slings and excluded the TVT-Secur found no significant difference in cure rates between full-length slings and mini slings [25].

Two recently published RCTs with 12-month follow-up data have compared the MiniArc single-incision mini sling (which is placed in the obturator internus) to the Monarc full-length transobturator midurethral sling and demonstrated noninferiority [26,27]. One of these studies demonstrated reduced pain and recovery time with the mini sling [26]. Two-year follow-up was presented at the 2014 American Urogynecologic Society (AUGS)/International Urogynecological Association (IUGA) Scientific Meeting and continued to demonstrate noninferiority [28,29]. A recent single-center RCT performed Ophira mini slings under local anesthesia with no postoperative catheterization compared with outside-in transobturator slings under regional anesthesia with postoperative catheterization and



**Table 1.** Summary of comparative trials of different categories of midurethral sling

Comparison	Important studies	Summary
Retropubic vs transobturator	Trial of midurethral slings RCT [8]	Similar subjective and objective success rates; higher voiding dysfunction with retropubic and higher neurologic symptoms in transobturator slings
	Society for Gynecologic Surgeons (SGS) review [13 <sup>***</sup> ]	Similar efficacy and satisfaction; higher bladder perforations, pain, urinary tract infections, overactive bladder with retropubic and higher erosion, groin pain, and vaginal perforation with transobturator slings
	Cochrane review [4]	Slightly higher objective cure with retropubic slings but no difference in subjective cure; higher blood loss, bladder perforations, voiding dysfunction with retropubic than transobturator slings
Retropubic top-down vs bottom-up	SPARC vs TVT RCT [18,19]	Similar efficacy and adverse events
	SGS review [13 <sup>***</sup> ]	Insufficient evidence
	Cochrane review [4]	Bottom-up has improved efficacy, less voiding dysfunction, bladder perforations, and mesh erosions
Transobturator inside-out vs outside-in	SGS review [13 <sup>***</sup> ]	Insufficient evidence
	RCT [20]	More sexual dysfunction with outside-in approach
Single incision vs full length	MiniArc vs Monarc RCT [26 <sup>**</sup> ]	Noninferiority; decreased pain and recovery time with single-incision slings
	MiniArc vs Monarc RCT [27]	Noninferiority
	SGS review [13 <sup>***</sup> ]	Improved cure rates with full-length slings
	Review [25 <sup>***</sup> ]	No difference in cure rates when excluding TVT-secure

RCT, randomized controlled trial; SPARC, suprapubic arc; TVT, tension-free vaginal tape.

found shorter operative times and less groin pain but inferior objective cure rates [30].

The idea that less mesh means less pain and less complications overall has not borne out. The anchors may contribute to pain and dyspareunia rates, and these slings have many of the same complications as full-length slings [31].

To summarize, some single-incision mini slings, such as the MiniArc, may be equivalent to full-length slings with some short-term advantages perioperatively but with less long-term follow-up regarding cure rates.

### INTRINSIC SPHINCTER DEFICIENCY

Although ISD was originally used to describe a condition of severe incontinence associated with a poorly mobile urethra and poor urethral function tests, the term is now commonly used to categorize women with SUI who just have low maximum urethral closure pressures (MUCPs) or low Valsalva leak point pressures (VLPPs) with no description of severity or urethral mobility. Whether these urethral function tests should be used to determine the type of sling remains controversial. The 'u' shape of retropubic slings has a theoretical advantage for closing a weak urethra compared with the flatter transobturator slings. In a multisite transobturator

vs retropubic RCT of 180 patients, neither VLPP nor baseline incontinence severity was associated with the development of any recurrent incontinence or recurrent SUI in patients receiving a TVT or TOT [32]. Others have found that preoperative MUCP and VLPP did not predict long-term (4-year) outcome after transobturator midurethral sling [33]. In the TOMUS trial of 597, wherein surgeons were blinded to the preoperative urodynamic results so that they could not adjust their operative procedures based on urodynamic data, women with lower quartile MUCPs or lower quartile VLPPs did have surgical failure rates nearly two-fold higher than those with higher urethral function tests, but this occurred in both the retropubic and transobturator treatment arms, and there was no evidence that retropubic procedures should be the procedure of choice in women with these poorer function tests [34]. In an RCT of women with urodynamically defined ISD treated with retropubic or transobturator midurethral slings, women who received an obturator sling had similar subjective cure assessed by quality-of-life questionnaires (the first listed primary outcome in the clinical trials registry), but inferior outcomes of the second primary outcome (need for repeat surgery) and the third primary outcome (urodynamic stress incontinence) [35]. The surgeons who determined the need for repeat

surgery were not blinded to the primary surgical procedure and a retropubic midurethral sling was their salvage operation for a failed midurethral sling.

To summarize, women with worse urethral function have lower success rates with either sling, but there is not conclusive evidence that these tests are needed to determine the route of midurethral sling. The authors do prefer retropubic slings for women with severe incontinence.

## CONCLUSION

A summary of comparative trials of different categories of midurethral slings can be found in Table 1. Both retropubic and transobturator full-length midurethral slings are appropriate in most patients for the surgical treatment of SUI. The decision to choose one or the other should be individualized based on patient and surgeon preference after counseling about the risks of each. Data are not sufficient to guide decision-making about single-incision mini slings or adjustable slings but suggest that the TVT-Secur may be inferior to full-length slings, and the MiniArc may be comparable.

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## Conflicts of interest

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- of special interest
- of outstanding interest

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